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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/773,697      | 02/06/2004  | Lasse L. Hessel      | 81421-4037          | 7795             |
| 28765           | 7590        | 11/03/2006           | EXAMINER            |                  |
| HEWITT, JAMES M |             |                      |                     |                  |
| ART UNIT        |             |                      | PAPER NUMBER        |                  |
|                 |             |                      | 3679                |                  |

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/773,697             | HESSEL ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | James M. Hewitt        | 3679                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 August 2006.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-45 is/are pending in the application.
  - 4a) Of the above claim(s) 5,6,9 and 10 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 7, 15-19, 24-39, 41, 43-45 is/are rejected.
- 7) Claim(s) 8,11-14,20-23,40 and 42 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 August 2006 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

This application contains claims 5-6 and 9-10 drawn to an invention nonelected with traverse in the reply filed 11/3/05. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed on 8/8/01. It is noted, however, that applicant has not filed a certified copy of the PCT/DK01/00529 application as required by 35 U.S.C. 119(b).

The certified copy was not received in the 8/10/06 reply. ***Drawings***

The drawings are objected to because: in Figure 11, '138' should be '38' and reference character 'A' is upside down. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several

Art Unit: 3679

views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claims 1-4, 7-8 and 11-45 are objected to because of the following informalities:

The preamble of claim 1 recites "A coupling *for* detachably coupling first and second devices", thus inferring that the first and second devices. Yet the body makes it clear that the first and second devices are positively claimed. Applicant is required to amend the preamble of claim 1 and its dependents to be consistent with the body of the claim(s).

For examination purposes, the first and second coupling devices have been considered to be claimed in combination with the coupling.

In claim 29, it is unclear as to how the second device can be said to be operably coupled to the pouch. Aren't the second device and the pouch one and the same?

In claim 33, "further comprising" should precede "releasing".

In claim 34, "further comprising" should precede "releasing".

Art Unit: 3679

In claim 35, it is unclear as to how the ostomy pouch relates to the first and second devices. Aren't the second device and the pouch one and the same? And the ostomy pouch should be related to the pouch recited in claim 29.

In claim 36, it is unclear as to how the stoma relates to the first coupling device. Aren't they one and the same?

In claim 36, it is unclear as to how the second device can be said to be operably coupled to the pouch. Aren't the second device and the pouch one and the same?

In claim 37, "further comprising" should precede "releasing".

In claim 38, "further comprising" should precede "releasing".

The preamble of claim 39 recites "A coupling *for* detachably coupling first and second devices", thus inferring that the first and second devices. Yet the body makes it clear that the first and second devices are positively claimed. Applicant is required to amend the preamble of claim 39 and its dependents to be consistent with the body of the claim(s). And note that the claim recites a pouch.

For examination purposes, the first and second coupling devices have been considered to be claimed in combination with the coupling.

The preamble of claim 40 recites "A coupling *for* detachably coupling first and second devices", thus inferring that the first and second devices. Yet the body makes it clear that the first and second devices are positively claimed. Applicant is required to amend the preamble of claim 40 and its dependents to be consistent with the body of the claim(s).

Art Unit: 3679

For examination purposes, the first and second coupling devices have been considered to be claimed in combination with the coupling.

The preamble of claim 41 recites “A coupling *for* detachably coupling first and second devices”, thus inferring that the first and second devices. Yet the body makes it clear that the first and second devices are positively claimed. Applicant is required to amend the preamble of claim 41 and its dependents to be consistent with the body of the claim(s).

For examination purposes, the first and second coupling devices have been considered to be claimed in combination with the coupling.

The preamble of claim 42 recites “A coupling *for* detachably coupling first and second devices”, thus inferring that the first and second devices. Yet the body makes it clear that the first and second devices are positively claimed. Applicant is required to amend the preamble of claim 42 and its dependents to be consistent with the body of the claim(s).

For examination purposes, the first and second coupling devices have been considered to be claimed in combination with the coupling.

The preamble of claim 43 recites “A coupling *for* detachably coupling first and second devices”, thus inferring that the first and second devices. Yet the body makes it clear that the first and second devices are positively claimed. Applicant is required to amend the preamble of claim 43 and its dependents to be consistent with the body of the claim(s).

For examination purposes, the first and second coupling devices have been considered to be claimed in combination with the coupling.

In claim 44, lines 2-3, "the axis" lacks proper antecedent basis.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 15, 17, 19, 24-39, 41 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,785,695 (Sato et al).

With respect to claim 1 and with particular reference to Figure 5, Sato et al disclose a coupling for detachably coupling first and second devices comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, with the first coupling part having a circumferential coupling groove (17) defined by a radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture, wherein at least a portion of the first disc overlaps at least a portion of the second disc (in the radial direction); and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the apertures of the first and second discs, respectively, and extending

Art Unit: 3679

mainly in a cross direction of each respective disc, wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part when the devices are operably connected to each other.

With respect to claim 2, wherein the radial exterior wall of the coupling groove includes a circumferential projection (bulb) facing radially inwards and defining an offset.

With respect to claim 3, wherein at least a portion of the free end face of the coupling groove abuts closely against the first disc when the devices are operably connected to each other.

With respect to claim 4, wherein the radial exterior wall of the coupling groove is longer than the radial interior wall of the coupling groove when viewed in cross section.

With respect to claim 7, wherein the first and second coupling collars are arranged to be pressed together between the radial interior wall and exterior wall of the first coupling part when the devices are operably coupled.

With respect to claim 15, wherein the first disc has a greater diameter than the second disc.

With respect to claim 17, wherein at least the second disc is reinforced with at least one circumferential rib (inner collar of second disc).

With respect to claim 19, further comprising locking means (outer collar of first disc) for locking the first and second discs together when the devices are operably coupled together.

With respect to claim 24, wherein the first disc has a first section (portion of pouch 10) extending radially outwards from its aperture in a direction mainly perpendicular to the axis, and a conic section (portion of pouch 10, see Fig. 1b) extending radially outwards of and continuous with the first section.

With respect to claim 25, wherein the second disc (including pouch 15) extends conically outwards from the aperture of the second disc (see Fig. 1b).

With respect to claim 26, wherein the first coupling part is an implant for implantation around a stoma of an animal or human body.

With respect to claim 27, wherein the second coupling part is placed inside a pouch (10) for coupling with the implant with the coupling collars extending out through an aperture in the pouch.

With respect to claim 28, wherein an inside of an edge section along the aperture of the pouch is closely joined with an outer side of a radial first section of the first disc.

With respect to claim 29, Sato et al disclose a method for application of a coupling according to claim 1, comprising joining the two discs of the second coupling part, placing the second coupling part is placed inside a pouch, and joining the inside of an area around an aperture of the pouch with and fastened to the first disc with the coupling collars extending out through the aperture of the pouch, wherein the second disc is operably connected to the pouch.

With respect to claim 30, further comprising pushing the two coupling collars of the second coupling part together are pushed into the coupling groove of the first coupling part.

With respect to claim 31, placing the radial exterior wall of the first coupling part in a guide groove in the first disc of the second coupling part while the second coupling part is in an opened position, and thereafter positioning the second coupling part in a closed position, wherein the radial exterior wall forms the outer definition of the coupling groove.

With respect to claim 32, which further comprises uncoupling the parts by releasing an engagement between the coupling parts by manipulation of the first disc.

With respect to claim 33, releasing the engagement between the two coupling parts by distally displacing the first disc.

With respect to claim 34, releasing the engagement between the two coupling parts by affecting the first disc with radially opposite compressive forces in peripheral areas.

With respect to claim 35, Sato et al discloses an ostomy pouch (10).

With respect to claim 36, Sato et al discloses a method for application of the coupling according to claim 1, comprising implanting the first coupling part around a stoma, wherein the first coupling part in the form of an annular implant having a projecting section with the coupling groove, and coupling an ostomy pouch (10) to the implant by pushing the two coupling collars of the second coupling part into the coupling groove of the first coupling part.

With respect to claim 37, releasing an engagement between the two coupling parts is manipulation of the first disc.

With respect to claim 38, releasing an engagement between the two coupling parts manipulation of a locking means (collars and groove) for disengaging the first and the second disc.

With respect to claim 39 and with particular reference to Figure 5, Sato et al disclose a coupling for detachably coupling first and second devices comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, with the first coupling part having a circumferential coupling groove (17) defined by a radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture; a pouch (15), wherein at least a portion of the pouch is positioned between the first and second disc; and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the apertures of the first and second discs, respectively, and extending mainly in a cross direction of each respective disc, wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part when the devices are operably connected to each other.

With respect to claim 41 and with particular reference to Figure 5, Sato et al disclose a coupling for detachably coupling first and second devices comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, with the first coupling part having a circumferential coupling groove

(17) defined by a radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture; locking means (outer collar of first disc) for locking the first and second discs together; and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the apertures of the first and second discs, respectively, and extending mainly in a cross direction of each respective disc, wherein the second coupling collar extends through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part when the devices are operably connected to each other.

With respect to claim 43 and with particular reference to Figure 5, Sato et al disclose a coupling for detachably coupling first and second devices comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, with the first coupling part having a circumferential coupling groove (17) defined by a radial interior and exterior walls and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture; and first and second coupling collars (inner collar of first disc and outer collar of second disc) designed around the apertures of the first and second discs, respectively, and extending mainly in a cross direction of each respective disc; wherein the first and second disc each have portions (portion of pouch 10 and portion of pouch 15) which extend radially outward from the first and second coupling collars, respectively; wherein the second coupling collar extends

through the aperture of the first disc in the same direction as the first coupling collar, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part when the devices are operably connected to each other.

With respect to claim 44, wherein the first disc has a first section (portion of pouch 10) extending radially outwards from its aperture in a direction mainly perpendicular to the axis, and a conic section (portion of pouch 10, see Fig. 1b) extending radially outwards of and continuous with the first section.

With respect to claim 45, wherein the second disc (including pouch 15) extends conically outwards from the aperture of the second disc (see Fig. 1b).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,785,695 (Sato et al).

Regarding claim 16, Sato et al fail to teach that the second disc is more rigid than the first disc. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second disc of a material more rigid than the first since it has been held to be within the general skill of a worker in the art to

select a known material on the basis it suitability for the intended use as a matter of obvious design choice.

Regarding claim 18, Sato et al fail to teach that the first disc is made of a transparent material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first disc of a transparent material since it has been held to be within the general skill of a worker in the art to select a known material on the basis it suitability for the intended use as a matter of obvious design choice.

#### ***Allowable Subject Matter***

Claims 8, 11-14 and 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note that the allowability of the above claims is also contingent upon overcoming the above-noted objections (see ***Claim Objections*** above).

#### ***Response to Arguments***

Applicant's arguments filed 8/10/06 have been fully considered but they are not persuasive.

Regarding claim 1, Applicant argues that Sato et al does not disclose the limitation "wherein at least a portion of the first disc overlaps at least a portion of the second disc". Examiner disagrees. Refer to the above rejection of claim 1.

Regarding claim 39, Applicant argues that Sato et al does not disclose the limitation "a pouch, wherein at least a portion of the pouch is positioned between the first and second disc". Examiner disagrees. Refer to the above rejection of claim 39.

Regarding claim 43, Applicant argues that Sato et al does not disclose the limitation "wherein the first and second disc each have portions which extend radially outward from the first and second coupling collars". Examiner disagrees. Refer to the above rejection of claim 43.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

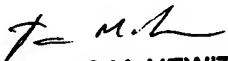
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Hewitt whose telephone number is 571-272-7084.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Stodola can be reached on 571-272-7087. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMH  
10/26/06

  
JAMES M. HEWITT  
PRIMARY EXAMINER